

**REMARKS**

Claims 1-11, 19, and 26-34 are pending. Claims 12-18 and 20-25 have been canceled without disclaimer or prejudice to pursuing their subject matter in a continuing application. Claims 31-34 have been added to cover preferred embodiments, support for which can be found in Fig. 1, paragraphs 19 and 50, the working examples, and the original claims of the present specification. Other claims have been amended to correct informalities noted in the action and to use parallel structure. No new matter has been introduced by these amendments.

Claims 12-18 have been rejected under 35 U.S.C. 102(b) as anticipated by Ring '400. Claims 1-11 and 19-31 have been rejected under 35 U.S.C. 103(a) as obvious over Ring '400 in view of Augustine. Reconsideration of the rejections is respectfully requested.

The anticipation rejection of claims 12-18 is rendered moot by their cancellation. Accordingly, the sole remaining art rejection is the obviousness rejection based on Ring '400 in view of Augustine. The underlying rationale of the obviousness rejection is that discovering a type of microbial cellulose that has the dual ability to donate and absorb sufficient amounts of fluid to yield an effective treatment for a chronic wound amounts to nothing more than "optimization." Applicants respectfully point out that the record amply demonstrates the unobviousness of the presently claimed invention.

The presently claimed invention solves an unrecognized problem in the art. An invention based on the discovery of a hitherto unrecognized problem in the prior art may be unobvious even though the solution to the problem, once recognized, is obvious. *In re Spinnoble*, 160 USPQ 237 (CCPA 1969). The present applicants discovered that other wound dressings could not effectively donate and absorb liquid at levels sufficient to treat chronic wounds. See Fig. 2 of the present application, showing that Nugel, Clearsite, and Flexigel products donate less than the half of the amount of liquid as the presently claimed invention (referred to as XCell in Fig. 2). Further, the present applicants experimented with different types of microbial cellulose, such as those exemplified in Ring '400, and found that they donated adequately but could not absorb adequately for purposes of treating a chronic

wound or that they failed to donate adequately in cases where Ring taught the addition of further ingredients that interfered with moisture donation. See the attached Rule 132 Declaration of Chris Damien, showing results obtained with each of working examples 2, 4, 7, and 8 of Ring '400.<sup>1</sup> Rather than follow the teaching of Ring '400 Ex. 9 to add channels to increase absorption, the present inventors instead recognized that it might be possible to take advantage of the unique nature of microbial cellulose to lower the liquid content to a point where it would both donate and absorb liquid in adequate amounts to treat a chronic wound.

No prior art reference gives any motivation to reduce liquid content with the goal or expectation that absorption would increase to a level adequate for treating a chronic wound. Ring did not present any results relating to treatment of chronic wounds. It is clear from the experimental results of Ring's working examples presented in the attached copy of the executed Rule 132 Declaration from related Ser. No. 10/132,171 that they are not as effective for treating a chronic wound as the presently claimed invention, which provides balanced donation and absorption needed for chronic wounds. There is no teaching offered in the rejection to support the motivation to reduce liquid content in Ring's working examples to reach a level that would enable sufficient absorption to treat a chronic wound. Clearly, this is not "optimization." Rather, it is an elegant solution to a problem not recognized in the prior art. Namely, the inventors recognized that they could give up some excess donation capacity in exchange for greater absorption capacity to achieve a dressing that could perform both functions adequately to treat a chronic wound.

The teaching of a broad range of cellulose/liquid contents in Ring '400 does not provide motivation for selecting an extreme end of the range for use in treating a particular class of wounds, i.e., chronic wounds. The rejection never offers a motivation to select the extreme end of the non-exemplified cellulose content range taught by Ring '400 for the purpose of treating chronic wounds. The rejection may not ignore the importance of the present method claims which are directed to treating chronic wounds. Ring '400 nowhere

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<sup>1</sup> Although the instant action does not cite a particular example of Ring '400, it is presumed that the action relies upon the same examples (2, 4, 7, and 8) cited as being relevant by Exr. Webman in related co-pending Ser. No. 10/132,171. Hence, applicants rely here upon a copy of the Rule 132 Declaration submitted in Ser. No. 10/132,171, which addresses the only relevant examples cited by Exr. Webman in Ser. No. 10/132,171.

disclosed that there was a relationship of any kind between cellulose content and donation and absorption together.

Claims 31-34 are separately patentable. Claims 32 and 33 are directed to particular embodiments of claim 1 wherein cellulose and water are the essential ingredients (claim 32) of the dressing (thus excluding other ingredients that would materially alter the donation and absorption capacity of the dressing but permitting inclusion of non-essential ingredients such as preservatives) and the only ingredients of the dressing (claim 33).

In addition, claim 34 relates to the discovery of the present inventors that microbial cellulose dressings are capable of reducing pain associated with wounds in comparison to non-adhesive gauze dressings. The prior art in no way suggests this method would be possible.

Inherency may not be used in this context to reject a method claim, especially in the context of an obviousness rejection. Applicants request that the PTO pay particular attention to the preamble of new claim 34, “reducing pain”, and to the connection of this preamble to the claim’s active step of administering to a “subject in need thereof” in light of the Federal Circuit’s 2001 holding in *Rapaport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001). The *Rapaport* holding was summarized as follows in *Jansen v. Rexall Sundown*, 342 F.3d 1329 (Fed. Cir. 2003):

A similar issue arose in *Rapaport*, an interference proceeding before the PTO's Board of Patent Appeals and Interferences. The count in that case read as follows:  
A method *for treatment of sleep apneas* comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof *to a patient in need of such treatment* ....

254 F.3d at 1056 (emphases added). On appeal we gave weight to the ordinary meaning of the preamble phrase “for treatment of sleep apneas,” interpreting it to refer to sleep apnea, *per se*, not just “symptoms associated with sleep apnea.” *Id.* at 1059. *Rapaport* argued that the count was unpatentable on the ground that a prior art reference disclosed that a form of the compound recited in the claim could be administered, not for treatment of sleep apnea itself, but for treatment of anxiety and breathing difficulty, a symptom of apnea. *Id.* at 1061. We rejected that argument, stating, “There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea *with the intent to cure the*

*underlying condition.” Id.* (emphasis added). Thus, the claim was interpreted to require that the method be practiced with the intent to achieve the objective stated in the preamble.

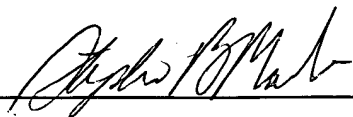
Viewed properly in the light of this controlling precedent, it is clear that none of the prior art disclosures relating to microbial cellulose dressings used for other purposes could anticipate the presently claimed method. Ring ‘400 presents no results of any kind. There is no manifestation of any intent in Ring ‘400 or Augustine to reduce pain associated with a wound. In short, applicants have properly redrafted claim 34 as a new use, which is separately patentable on the basis of the new use.

Claims 1-31 have been rejected under the second paragraph of 35 U.S.C. 112 for indefiniteness. After considering each objection noted in the action, the claims have been amended to clarify the invention. Accordingly, withdrawal of the rejection is requested.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

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